EVERYWAY EVERYWAY MEDICAL INSTRUMENTS CO.,LTD.
3Fl., No. 5, Lane 155, Sec. 3,Peishen Rd, Shen Keng Hsiang, Taipei Hsien, Taiwan,

OCT 21 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of SMDA 1990 and 21 CFR 807.92 on August 03, 2011.

The assigned 510(k) number is: K112415

1. Submitter's Identifications:

   Establishment:EVERYWAY MEDICAL INSTRUMENT CO., LTD.
   Address: 3Fl., No. 5, Lane 155, Sec. 3, Peishen Rd., Shenkeng Hsiang, Taipei Hsien 222, Taiwan
   Registration Number: 9616877
   Contact Person: Robert Tu
   Phone : 886-2-2662-0038
   Fax No: 886-2-2664-5566
   e-mail : tu922@ms35.hinet.net

2. Name of the Device:
   LIFECARE Arm & Leg Pain Relief System, model EV-820.

3. Information of the 510(k) Cleared Device (Predicate Device):
   - The Prizm 5000-Z System (K033122)
   - Well-Life OTC TENS for Arm & Leg Pain Relief, model WL-2407(K091757)

4. Classification Information:
   Trade/Device Name: LIFECARE Arm & Leg Pain Relief System, model EV-820.
   Regulation Number: 21 CFR 882.5890
   Regulation Name: Transcutaneous Nerve Stimulator
   Regulatory Class: II
   Product Code: NUH

5. Device Description:

   The LIFECARE Arm & Leg Pain Relief System, model EV-820 is the model of OTC TENS intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities. Basically the stimulation model EV-820 is completely identical to that of model as mentioned in our previous submission of Everyway Low Back Pain Relief System, model EV-820(K110716). To change the indication for use for the treatment location as the chosen predicate devices, Everyway changed the design of electrode.

   For the device included in this submission, we use the following of our 510(K) legally marketed predicate garment electrodes and self adhesive electrode :
   <1>K103716, "Lifecare HC-88 Series Conductive Garments" together with our Lifecare TKF4080(4x8 CM)/K083302 self adhesive electrode..

   EV-820 is a selectable dual channel, 9V battery operated TENS device with the following features:
   <1> The operation function is dual channels completely identical to the model being modified, EV-820 for low back pain relief(K110716).

<2> For the stimulation electrode, LIFECARE Arm & Leg Pain Relief System, model EV-820 uses our K103716 " Lifecare HC-88 Series Conductive Garment Electrodes" together with our Lifecare TKF4080(4x8 CM)/K083302 self adhesive electrode as standard accessories.
<3> The output waveform is selectable pre-programming change among P1~P8.
<4> The output strength is adjustable at 0~80 mA, with maximum setting time 60 minutes counting from switching ON.
<5> The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low warning.

With the combination of the main device parts, the device can be worn on the Arm & Leg part of user so as to place the stimulation pads on the treatment location of Arm & Leg for over the counter use without prescription in temporary relief of pain associated with sore and aching muscles in the Arm & Leg.

6. Intended Use:

The LIFECARE Arm & Leg Pain Relief System, model EV-820 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

7. Comparison to the 510(k) Cleared Device (Predicate Device):

For the substantial equivalent comparison, the power level testing comparison with the chosen 510(K) cleared device, Prizm 5000-Z system and Well Life WL-2407, was conducted via using 1K ohm loading resistance for the garment electrodes. The comparison result is as the following table:

Current Density comparison: (Unit : mA/cm^2)

Electrode Type	Glove	Sleeve& Knee	Sock
Everyway EV-820	0.00337	0.00386	0.00271
Well-life WL-2407	0.00337	0.00386	0.00271
Prizm 5000-Z	0.00340	0.00385	0.00274

Power Density Comparison : (Unit : W/cm^2)

Electrode Type	Glove	Sleeve & Knee	Sock
Everyway EV-820	0.00032	0.00036	0.00025
Well-life WL-2407	0.00032	0.00036	0.00025
Prizm 5000-Z	0.00064	0.00072	0.00051

Based on this comparison result, we made a acknowledge that our EV-820 model has the same output level as that of WL-2407, but has a lower current and power density than that of Prizm 5000-Z system while using the same electrode. This result is completely similar to the comparison of WL-2407 and Prizm 5000-Z system. Therefore; we concluded that the Everyway Arm & Leg Pain Relief system is substantially equivalent to Well-Life WL-2407(K091757) and the Prizm 5000-Z system (K033122) in the feature of stimulation output characteristics.

8. Discussion of Non-Clinical Tests Verification Activities Performed to Determine the Safety and Performance of EV-820 are as the followings:
   1> Performance Compliance Test according to ANSI/AAMI NS4 conducted by manufacturer
   2> Usability Study Report according to IEC 60601-1-6 conducted by manufacturer.
   3> Electrical Compliance Test according to IEC 60601-1 by accredited laboratory.
   4> EMC Compliance Test according to IEC 60601-1-2 by accredited laboratory.
   5> Biocompatibility Test for the support belt and stimulation electrode according to ISO 10993-5 & ISO 10993-10 by accredited laboratory.

9. Discussion of Clinical Test Validation Activities Performed to Determine the Effectiveness of Device are as the followings:
   No particular Clinical Test was conducted for LIFECARE Arm & Leg Pain Relief System, model EV-820.

10. Conclusions
    The LIFECARE Arm & Leg Pain Relief System, model EV-820, has the same intended use and technological characteristics as the cleared device of The Prizm 5000-Z System (K033122) and Well-Life OTC TENS for Arm & Leg Pain Relief, model WL-2407(K091757). Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

    In the other words, LIFECARE Arm & Leg Pain Relief System, model EV-820 is substantial equivalent with The Prizm 5000-Z System (K033122) and Well-Life OTC TENS for Arm & Leg Pain Relief, model WL-2407(K091757).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 21 2011

Everyway Medical Instruments Co., LTD.
c/o Mr. Robert Tu
3Fl. No.5 Lane 155, SEC 3
Peishen Rd, Shenkeng Hsiang
Taipei Hsien 222
Taiwan

Re: K112415
Trade/Device Name: LIFECARE Arm & Leg Pain Relief System model EV-820
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: August 19, 2011
Received: August 22, 2011

Dear Mr. Tu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K112415

Device Name: LIFECARE Arm & Leg Pain Relief System, model EV-820.

Indications For Use:

The LIFECARE Arm & Leg Pain Relief System, model EV-820 is intended for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities

Prescription Use ____ OR Over-The-Counter Use __√__

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Page 1 of 1

510(k) Number K112415